The opinion in support of the decision being entered today is <u>not</u> binding precedent of the Board

Paper 12126

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

ALBERTO STAMPA, PELAYO CAMPS, GLORIA RODRIGUEZ, JORDI BOSCH and MARIA DEL CARMEN ONRUBIA

Junior Party,

٧.

WILLIAM P. JACKSON Senior Party.

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PAT & T.M. OFFICE BOARL OF PATENT APPEALS AND INTERFERENCES

Patent Interference Nos. 105,069 and 105,212

ON BRIEF

Before: McKELVEY, Senior Administrative Patent Judge, and SCHAFER and

LORIN, <u>Administrative Patent Judges</u>.

LORIN, Administrative Patent Judge

DECISION - PRIORITY - Bd.R. 125(a)

I. Introduction

This is a priority decision in interferences 105,069 and 105,212.

The question is whether Stampa et al., the junior party, has overcome the presumption that Jackson, the senior party, first invented the interfering subject

matter of Count 1 of both interferences by a preponderance of the evidence.

Stampa alleges that it actually reduced the invention of the counts to practice no later than May 7, 1996, which is earlier than the February 26, 1997, filing date to which Jackson is accorded priority benefit. However, Stampa presents no convincing evidence to corroborate the inventors' testimony said to show that an experiment meeting the invention of the count was performed on May 7, 1996. For that reason and other reasons discussed below, we hold that Stampa has not overcome the presumption that Jackson first invented the interfering subject matters of Count 1 of both interferences.

II. Findings of Fact

A. The Parties

- The junior party is Alberto Stampa, Pelayo Camps, Gloria Rodriguez,
 Jordi Bosch and Maria Del Carmen Onrubia [Stampa].
- 2. The real party in interest with respect to Stampa is Medichem, S.A. (Paper 4).
- 3. Stampa is involved in the interferences based on the following patent and reissue application:
 - U.S. Patent 6,084,100 ['100], granted July 4, 2000, based on application 09/058,837, filed April 13, 1998; and
 - U.S. Reissue Application 10/234,659 ['659], filed September 3, 2002.

- 4. Stampa's '100 patent and '659 reissue application indicate that the inventors of the subject matter claimed in Stampa's patent and reissue application are:
 - Alberto Stampa [Alberto Stampa];
 - Pelayo Camps [Camps];
 - Gloria Rodriguez [Rodriguez];
 - Jordi Bosch [Bosch]; and,
 - Maria Del Carmen Onrubia [Onrubia],

all of Spain.

- 5. The senior party is William P. Jackson [Jackson].
- 6. The real party in interest with respect to Jackson is Rolabo S.L. (Paper 8).
- 7. Jackson is involved in the interferences based on the following patent and application:
 - U.S. Patent 6,093,827 ['827], granted July 25, 2000, based on application 09/383,078, filed August 26, 1999; and
 - U.S. Application 09/525,894 ['894], filed March 15, 2000.
- 8. Jackson's '827 patent and '894 application indicate that the inventor of the subject matter claimed in Jackson's patent and application is William P. Jackson of the United Kingdom.

B. Interference 105,069

- 9. Interference 105,069¹ involves
 - Stampa's '659 reissue application;
 - Jackson's '827 patent; and,
 - Jackson's '894 application.

Paper 76, p. 1.

- 10. Count 1, the sole count in the interference, is claim 17 of Jackson's '827 patent. It reads as follows:
 - 17. A process as claimed in claim 1 for preparing Loratadine.
 - [1. A process for preparing 5,6-dihydro-11 H-dibenzo[a,d]cyclohept-11-enes comprising reacting a dibenzosuberone or an aza derivative thereof with an aliphatic ketone in the presence of a low valent titanium wherein said low valent titanium is generated by zinc.]

Paper 76, p. 1.

- 11. The claims of the parties which correspond to Count 1 are:
 - Stampa's '659 reissue application: claims 1-182;
 - Jackson's '827 patent: claims 1-173; and,
 - Jackson's '894 application: claims 1-284

Paper 76, p. 2.

¹ Interference 105,069 was declared on December 11, 2002 (Paper 1) and redeclared on April 14, 2004 (Paper 76). See Stampa v. Jackson, 65 USPQ2d 1942 (Bd. Pat. App & Int. 2002) and Stampa v. Jackson, ____ USPQ2d ____, Paper 76 (Bd. Pat. App. & Int. Apr. 14, 2004).

² In other words, all the claims in Stampa et al.'s reissue application.

³ In other words, all the claims in Jackson's patent.

⁴ In other words, all the claims in Jackson's application.

C. 105,212

- 12. Interference 105,212⁵ involves
 - Stampa 's '659 reissue application;
 - Stampa's '100 patent; and,
 - Jackson's '894 application.

Paper 76, pp. 1-2.

- 13. Count 1, the sole count in the interference, is claim 17 of Jackson's '894 application. It reads as follows:
 - 17. A process as claimed in any preceding claim⁶ for preparing Loratadine.
 - [1. A process for preparing 5,6-dihydro-11 H-dibenzo[a,d]cyclohept-11-enes consisting essentially of reacting a dibenzosuberone or an aza derivative thereof with an aliphatic ketone in the presence of a low valent titanium wherein said low valent titanium is generated by zinc.]
- 14. The claims of the parties which correspond to Count 1 are:

• Stampa's '659 reissue application: claims 1-18;

• Stampa '100 patent: claims 1-137; and,

Jackson's '894 application: claims 1-28.

D. Accorded Benefit

⁵ Interference 105,212 was declared on April 14, 2004 (Paper 76 of 105,069).

⁶ Consistent with the Decision on Motions, Paper 69, p. 28, footnote 6, the focus will remain on Jackson application claim 17's dependency on claim 1.

⁷ In other words, all the claims in Stampa's patent.

- 15. The Redeclaration (Paper 76, p. 2, Fact 5.) states that "[t]he accorded priority benefit dates set forth in the Notice Declaring Interference, Paper 1, remain in effect."
- 16. Accordingly, with respect to both interferences,
 - Stampa's '100 patent is accorded the benefit of U.S. Provisional Application 60/048,083, filed April 13, 1998. Paper 1, p. 18;
 - Stampa '659 reissue application is accorded the benefit of U.S. Patent 6,084,100, issued July 4, 2000, based on U.S. Application 09/058,837, filed April 13, 1998. Paper 1, p. 17;
 - Jackson's 827 patent is accorded the benefit of PCT Application PCT/GB98/00605, filed February 26, 1997, and UK Application 9703992, filed February 26, 1997. Paper 1, p. 19; and,
 - Jackson's '894 application is accorded the benefit of PCT Application PCT/GB98/00605, filed February 26, 1997, and UK Application 9703992, filed February 26, 1997. Paper 1, p. 20.
- 17. Because Jackson is accorded the benefit of an earlier filing date (<u>i.e.</u>, February 26, 1997), Stampa is the Junior Party and Jackson is the Senior Party in both interferences.

E. Jackson's Case on Priority⁸

- 18. Jackson's case on priority is set forth in its Principal Brief on Priority starting on line 1, page 3 and ending on line 15, page 5. Paper 79.
- 19. Jackson argues that "[t]he evidence establishes that Jackson conceived of the claimed invention [sic, invention of the count] no later than August 19, 1996,

and reduced the invention to practice no later than October 7, 1996." Paper 79, page 5, lines 13-15.

- 20. Jackson does not discuss diligence.
- 21. Accordingly, Jackson's case on priority alleges:
 - conception no later than August 19, 1996; and,
 - actual reduction to practice no later than October 7, 1996.

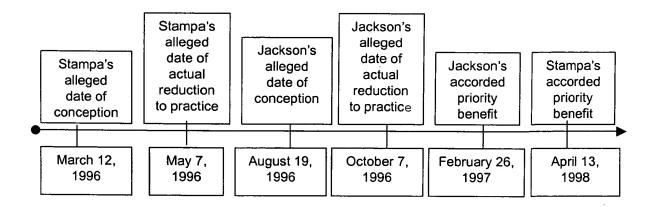
F. Stampa's Case on Priority

- 22. Stampa's case on priority is set forth on pages 9-14 of its Principal Brief on Priority. Paper 81.
- 23. Therein, Stampa argues that it "reduced the invention to practice by preparing loratedine according to the process of Count 1 no later than May 7, 1996," p. 9, and, "conceived of the invention corresponding to Count 1 no later than March 12, 1996 and exercised diligence in reducing it to practice between March 27 and May 7, 1996," p. 12.
- 24. Accordingly, Stampa's case on priority alleges:
 - conception no later than March 12, 1996;
 - actual reduction to practice no later than May 7, 1996; and,
 - diligence from conception to actual reduction to practice.

⁸ Because the evidence, when considered in light of the arguments made in Stampa's brief on priority, does not establish priority for Stampa, we have found it unnecessary to consider Jackson's brief in opposition (Paper 83) or Stampa's reply brief (Paper 86).

F. Priority Position of the Parties in the Interferences

25. The priority position of the parties in interferences 105,069 and 105,212 is the same. Based on accorded benefits and the alleged dates of conception and actual reduction to practice, the priority position of the parties in the interferences can be illustrated with the following timeline:



- 26. A rebuttable presumption exists that the inventors have invented the interfering subject matters of Count 1 of both 105,069 and 105,212 in the order of the dates of their accorded benefit, 37 CFR § 41.207(a)(1); that is, Jackson is presumed to have invented the interfering subject matters of both Count 1's on February 26, 1997, and Stampa is presumed to have invented the interfering subject matters of both Count 1's later, on April 13, 1998.
- 27. To prevail on priority, Stampa must establish by a preponderance of the evidence that it invented the interfering subject matters of both Count 1's prior to February 26, 1997. Stampa, the junior party, has the ultimate burden to prove priority. Brown v. Barbacid, 276 F.3d 1327, 61 USPQ2d 1236 (Fed. Cir. 2002).

- 28. May 7, 1996 is the date, no later than which, Stampa alleges it reduced the invention of the counts to practice.
- 29. Jackson has not alleged a date of conception prior to May 7, 1996.
- 30. Accordingly, "priority of invention goes to the first party to reduce [the] invention to practice" Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998).
- 31. Stampa will have overcome the presumption that Jackson first invented the interfering subject matters of Count 1 of both interferences and would be entitled to prevail in the interferences if Stampa can prove by a preponderance of the evidence, 37 CFR § 41.207(a)(1), that it actually reduced the invention of the counts to practice no later than May 6, 1997.
- 32. On the other hand, if Stampa cannot prove by a preponderance of the evidence it actually reduced the invention of the counts to practice no later than May 6, 1997, Jackson would be entitled to prevail in the interferences on the grounds that the presumption that Jackson first invented the interfering subject matter of Count 1 of both interferences on February 26, 1997 had not been overcome.
- G. Stampa's Argument for and Evidence in Support an Alleged Actual Reduction to Practice of No Later Than May 7, 1996
- 33. Stampa makes the following allegation in its Principal Brief on Priority, Paper 81, at page 9, line 17-18:

"Stampa [actually] reduced to [sic] the invention to practice by preparing loratedine according to the process of Count 1 no later than May 7, 1996."

- 34. Stampa's argument that it actually reduced the invention to practice no later than May 7, 1996, is presented in a section entitled
- [3.] a. Stampa Reduced the Invention of Count 1 to Practice No Later Than May 7, 1996which starts on page 9, line 19 and ends on page 12, line 13 of Stampa'sPrincipal Brief on Priority, Paper 81.
- 35. The section has two parts: a first part, which starts on page 9, line 19 and ends at page 10, line 21, arguing that an actual reduction to practice took place on May 7, 1996 and a second part, starting on page 10, line 22 and ending on page 12, line 13, directed to corroboration [see discussion in <u>I. Corroboration</u> below].
- 36. The first part, consisting of seven statements, argues that, on May 7, 1996, Lola Casas successfully carried out a trial designated as "LTD-L6" and obtained loratedine via the process of Count 1, as shown in Medichem's lab notebooks, and that this is verified by subsequent analysis of the product obtained.
- 37. The seven statements (<u>see</u> Principal Brief on Priority, Paper 81, page 9, line 19, to page 10, line 21), and the exhibits cited in support of thereof, are:

a. Statement 1:

"On that date [i.e., May 7, 1996], Medichem employee Lola Casas, working under the supervision and control of Gloria Rodriguez (a Medichem employee and named inventor on Stampa's '100 patent and reissue application), successfully carried out a trial of the process later claimed in the '100 patent and reissue application and made loratadine."

- "Exhibit 2020":
- "Exhibit 2021, ¶¶ 8, 13-15";
- "Exhibit 2024, ¶¶ 7, 10";
- "Exhibit 2027 at 58, 83-85";
- "Exhibit 2029 at "225-25"" [sic, 225 only];
- "Exhibit 2035":
- "Exhibit 2036";
- "Exhibit 2037"
- "Exhibit 2041 at 43-44"; and,
- "Exhibit 2044 at M 002797, 2800-02" [sic, there is no M 002797 or 2800-02 in Exhibit 2044].

c. Statement 2:

"The trial was denoted 'LTD-L6' in Medichem's laboratory notebooks to signify Medichem's sixth trial to obtain loratedine via the process of Count 1." Pp. 9-10.

- "Exhibit 2020";
- "Exhibit 2021 ¶ 13";
- "Exhibit 2024, ¶ 10";
- "Exhibit 2027 at 83-85";
- "Exhibit 2027 at M 002795" [sic, there is no M 002795 in Exhibit 2027]
- "Exhibit 2035"; and,
- "Exhibit 2044 at M 002795" [sic, there is no M 002795 in Exhibit 2044].

d. Statement 3:

"Unlike prior trials, however, in LTD-L6 Medichem used a starting material (Formula VII of claim 1 of Stampa's '100 patent and reissue application) that it purchased from a commercial supplier, rather than staring material it had produced itself and used in the five previous trials LTD-L1 through LTD-L5)."

- "Exhibit 2020";
- "Exhibit 2021, ¶¶ 8, 13";
- "Exhibit 2024, ¶¶ 7-10";
- "Exhibit 2027 at 58, 82-85";
- "Exhibit 2029 at 203, 225";
- "Exhibit 2035 at M 002797":
- "Exhibit 2041 at 44-45";
- "Exhibit 2042 at M 002758" [sic, there is no M 002758 in Exhibit 2042];
- "Exhibit 2043 at M 002766" [sic, there is no page M 002766 in Exhibit 2043]; and,
- "Exhibit 2044 at M 002797" [sic, there is no M 002795 in Exhibit 2044]...

e. Statement 4:

"Thin-layer chromatography (TLC) analysis of the LTD-L6 product showed the presence of loratadine."

- "Exhibit 2020";
- "Exhibit 2021";
- "Exhibit 2024, ¶ 10";
- "Exhibit 2035 at M 02797, 2800-02"
- "Exhibit 2044 at M 002797, 2800-02" [sic, there is no M 002795 in Exhibit 2044].

f. Statement 5:

"Medichem then sent a sample of the product of LTD-L6 to Dr. Pelayo Camps (a Professor of Organic Chemistry at the University of Barcelona and also a named inventor on the '100 patent and reissue application) for nuclear magnetic Resonance (NMR) spectroscopic analysis on May 9, 1996."

- "Exhibit 2021, ¶¶ 8, 14"; and,
- "Exhibit 2036".

g. Statement 6:

"A technician at the University of Barcelona carried out NMR analysis on the sample on May 16, 1996 at Dr. Camps' request."

- "Exhibit 2022, ¶¶ 8, 11"; and,
- "Exhibit 2039".

h. Statement 7:

"The NMR analysis showed conclusively that the product of LTD-L6 was loratedine, as confirmed by Dr. Camps in a report to Medichem dated June 3, 1996."

- "Exhibit 2021, ¶¶ 8, 15";
- "Exhibit 2022, ¶¶ 8, 10"; and,
- "Exhibit 2033"; and,
- "Exhibit 2037".
- 38. The cited exhibits are copies of the following documents:
 - Bosch's
 - i. Declaration of July 12, 2004 (Exhibit 2021);
 - ii. partial testimony in Civil Action, Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087 (S.D.N.Y. April 30, 2002) (Exhibit 2029);
 - Camps'
 - i. Declaration July 12, 2004 (Exhibit 2022);
 - ii. Report regarding NMR spectral data of June 3, 1996 (Exhibit 2037);
 - iii. graphs of May 15, 1996 (Exhibit 2039);
 - Onrubia's
 - i. Declaration of July 14, 2004 (Exhibit 2020);
 - partial testimony in <u>Medichem, S.A. v. Rolabo, S.L.</u>, 01 Civ. 3087, on April 29, 2002 (<u>Exhibit 2027</u>);
 - Rodriguez's
 - i. Declaration of July 13, 2004 (Exhibit 2024);
 - ii. partial testimony during deposition on November 9, 2001 (Exhibit 2041);
 - selected unnamed lab notebook pages for the period
 - i. February 7, 1996 to June 12, 1996 (Exhibit 2033);
 - ii. May 7-9, 1996 (Exhibit 2035);
 - iii. April 9, 1996 to June 10, 1996 (Exhibit 2043 untranslated);
 - iv. April 18-20, 1996 (Exhibit 2044 untranslated);
 - unnamed characterization request form dated May 9, 1996 (Exhibit 2036); and,
 - a provisional application (Exhibit 2042).

H. Review of the Evidence of Actual Reduction to Practice

- 39. Exhibit 2020 is a copy of a document, signed by Onrubia and dated July 14, 2004, entitled "Declaration of Dr. Maria Del Carmen Onrubia." It consists of 10 paragraphs covering 9 pages.
- a. The document includes what appears to be a reproduction of a portion of the testimony Onrubia gave at trial on April 29 and 30, 2002 before the Southern District of New York in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087.
 - b. ¶ 7 indicates that Onrubia testified that
- 1) Camps contributed to the idea of applying the McMurry reaction for obtaining loratedine at the end of 1995.
- 2) Mr. Pena participated in a meeting discussing projects in which the matter of loratedine was discussed.
- 3) Camps suggested a first test applying the "McMurry proceeding applied to the reaction of the compounds IV and VII ... using the organic solvent tertrahydrofuran in the presence of titanium tetrachloride with zinc."
- 4) Onrubia asked Camps to draft a report regarding the McMurry reaction and a report was hand delivered to her about a week after the meeting and a few days after the date on the report, which is said to be March 17, 1996.
- c. ¶ 10 indicates that Onrubia declares that all statements made on her own knowledge are true and statements made on information are believed to be true.
- 40. Exhibit 2021 is a copy of a paper, signed by Bosch and dated July 12, 2004, entitled "Declaration of Dr. Jordi Bosch" and consists of 16 paragraphs covering 12 pages.
- a. Exhibit 2021 is purported to be a portion of the testimony Bosch gave at trial on April 30 and May 1, 2002 before the Southern District of New York in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087.

- b. ¶ 8 ends with this question and answer:
 - Q: And May 7, 1996 was when Medichem first made the loratedine by the McMurray [sic?, McMurry] reaction?

 A: That is correct, yes.
 - 1) Bosch appears to have testified that trials LTD-L2, LTD-L3, LTD-L4, LTD-L5 produced impure products and in the case of LTD-L4, loratedine was not isolated.
- c. ¶ 13 discusses pages from a Medichem laboratory notebook purported to described the LTD-L6 trial. The discussion revolves around "Plaintiff's Trial Exhibit 21," pages M 002795, M 002797, and M 002800-02. [See Exhibit 2035 discussed below].
- d. ¶ 14 discusses an exhibit said to be a form dated May 9, 1996 requesting Camps to identify the product obtained in trial LTD-L6. The discussion revolves around "Plaintiff's Trial Exhibit 22." [See Exhibit 2036 discussed below].
- e. ¶ 15 discusses an exhibit said to be a report from Camps dated June 3, 1996 stating that the NMR spectral data of the product sample LTD-L6/P1 is loratedine. The discussion revolves around "Plaintiff's Trial Exhibit 24," pages M 002553. [See Exhibit 2037 discussed below].
- 41. <u>Exhibit 2022</u> is a copy of a paper, signed by Camps and dated July 12, 2004, entitled "Declaration of Professor Pelay Camps, Ph.D." It consists of 12 paragraphs covering 9 pages.
- a. Exhibit 2022 is purported to be a portion of the testimony Camps gave at trial on May 1 and 2, 2002 before the Southern District of New York in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087.
- b. ¶ 8 ends with Camps stating that "with certainty" Medichem first obtained loratedine on May 7, 1996.
- c. ¶ 10 discusses an exhibit said to be Camps' report of June 3, 1996 in which the results are given for the NMR analysis of the LTD-L6/P1 sample. The discussion revolves around "Plaintiff's Trial Exhibit 24," pages M 002553. [See Exhibit 2037 discussed below].

- d. ¶11 discusses an exhibit said to be the NMR spectra for the LTD-L6/P1 sample dated May 16, 1996. The discussion revolves around "Plaintiff's Trial Exhibit 23," pages M 002828-31. [See Exhibit 2039 discussed below].
- 42. <u>Exhibit 2024</u> is a copy of a paper, signed by Gloria Rodriguez and dated July 13, 2004, entitled "Declaration of Gloria Rodriguez." It consists of 12 paragraphs covering 9 pages.
- a. Exhibit 2024 is purported to be a portion of the deposition Rodriguez gave on November 9, 2001 as part of an action brought by Medichem in the Southern District of New York in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087.
- b. ¶ 7 states: "Deposition Exhibit 60, which I identified and discussed during my deposition testimony quoted in paragraphs 5 and 6 above, is a provisional patent application that I signed on May 16, 1997. Exhibit 2042. [See Exhibit 2042 discussed below.]"
- c. ¶ 10 states: "Deposition Exhibit 46, which I identified and discussed during my deposition testimony quoted in paragraph 8 above, are pages from the Laboratory Notebook No. 1 of Lola Casas, who was my assistant at Medichem at the time these notebook pages were prepared. Exhibit 2044. [See Exhibit 2044 discussed below.] These pages record laboratory trial LTD-12, which was performed from April 15 to April 20, 1996. Id. at M 002766. Trial LTD-12 was Medichem's second trial to obtain loratadine using a McMurry reaction. In this trial, we used a cycloheptanone intermediate (LTD-13-L2) that we had produced at Medichem. Id."

- d. ¶ 11° states: "Deposition Exhibit 47, which I identified and discussed during my deposition testimony quoted in paragraph 8 above, are pages from the Laboratory Notebook No. 1 of Lola Casas, who was my assistant at Medichem at the time these notebook pages were prepared. Exhibit 2045¹0. [See Exhibit 2035.] These pages record laboratory trial LTD-L6, which was performed on May 7, 1996. Id. at M 002795."
- 43. Exhibit 2027 is copy of the transcript of part of a bench trial in Medichem,
- S.A. v. Rolabo, S.L., 01 Civ. 3087, on April 29, 2002.
 - a. Page 58 indicates that Onrubia testified that
- 1) in response to a question asking "In 1996, who in the Research & Development Department at Medichem worked on the loratadine project", that "there was Dr. Bosch who was working as the chief of Research & Development who supervised Gloria Rodriguez who was responsible specifically for the loratadine project and she in turn supervised Lola Casas who was her assistant and I myself was cooperating in a collaborative role in my role as Director of Research & Development."
- 2) in response to a question asking "What is it [i.e., Plaintiff's No. 1]," that "It's an American patent which is owned by Medichem and it refers to a process for obtaining loratedine. Among the inventors I am one of the -- I am one of the inventors."
- b. Pages 82 85 indicate that Onrubia testified to Medichem's attempts to make loratedine, beginning in March 1996 until loratedine was successfully isolated in May. 1996.

⁹ This appears to be the only statement in the evidence cited by Stampa that would suggest that it was Lola Casas who conducted the LTD-L6 trial of May 7, 1996. ¶ 11 of Exhibit 2024 is not mentioned in the section on reduction to practice of Stampa's Principal Brief on Priority. While Exhibit 2024 is cited in the brief (see e.g., p. 9, line 22), only ¶¶ 7 and 10 are discussed. However, those paragraphs are not directed to the May 7, 1996 experiment.

¹⁰ Exhibit 2045 is not cited in Stampa's brief. However, our review of Exhibit 2045 reveals that it is identical to the untranslated pages of the lab notebook cited as Exhibit 2035. For that reason we refer to Exhibit 2035.

- 1) Pages 82 85 include the following testimony:
 - Q. Did there come a time when Medichem successfully made loratedine using the McMurry reaction used by Professor camps?
 - A. Yes, there did come such a time, and that was that took place during when we ran the sixth test.

The Court: And when was that?

The Witness: You mean test number 6? That was in may of 1996.

The Court: Okay.

- Q. Does that test have a name?
- A. Yes. The name of that test was LTD, which are the which correspond to the terminology used internally in Medichem for loratadine, following by an L, which stands for lab, followed by 6, which means sixth test.
- Q. Is there a written record of that?
- A. Yes.
- Q. What is that record?
- A. The lab notebook records, in which LTD L6 lab test is completely registered. Completely recorded.
- 44. Exhibit 2029 is copy of the transcript of part of a bench trial in Medichem,
- S.A. v. Rolabo, S.L., 01 Civ. 3087, on April 30, 2002.
- a. Page 203 indicates that Bosch testified that sample L-6 used a cycloheptanone intermediate from a commercial source.
- b. Page 225 indicates that Bosch turned to "page LTD L-6" of "Exhibit 21" [sic?, Plaintiff's Exhibit 21; see Exhibit 2035 discussed below] which he testified corresponded to a copy of lab trial LTD L-6 which Bosch stated was the first time loratedine was isolated.

- 45. <u>Exhibit 2033</u> consists of, in the following order:
- (1) an untranslated copy of eighty-nine pages of a lab notebook stamped Plaintiff's Exhibit 88;
- (2) a copy of an affidavit from Heather Barbara Clifford stating that attached Exhibit A is a translation she believes to be a true Catalan to English translation of the document stamped M 002599 M 002640, M 002644 M 002650, M 002666 M 002667, M 002672, M 002684 M 002686, M 002758 M 002763, M 002703 M 002704, M 002773 M 002777, M 002754 M 002757, M 002752 M 002753, M 002832 M 002846;
 - (3) a sheet marked "Exhibit A";
 - (4) a copy of the translation, and:
- (5) a copy of lab notebook pages stamped M 002599 M 002640, M 002644 M 002650, M 002666 M 002667, M 002672, M 002684 M 002686, M 002758 M 002763, M 002703 M 002704, M 002773 M 002777, M 002754 M 002757, M 002752 M 002753, M 002832 M 002846, which are identical to (1).
- a. The translation of lab notebook page M 002599 states, at the top of the page, "LTD -9 L1" and "Feb. 7, 1996". This is followed by three pages appearing to describe an experiment and its results.
- b. The translation of lab notebook page M 002603 states, at the top of the page, "LTD 10 L1" and "Feb. 8, 1996". This is followed by three pages appearing to describe an experiment and its results.
- c. The translation of lab notebook page M 002607 states, at the top of the page, "LTD 11 L1" and "Feb. 12, 1996". This is followed by four pages appearing to describe an experiment and its results.

- d. The translation of lab notebook page M 002612 states, at the top of the page, "LTD 12 L1" and "Feb. 13, 1996". This is followed by two pages appearing to describe an experiment and its results.
- e. The translation of lab notebook page M 002615 states, at the top of the page, "LTD -9 L12" and "Feb. 27, 1996". This is followed by two pages appearing to describe an experiment and its results.
- f. The translation of lab notebook page M 002618 states, at the top of the page, "LTD 10 L2" and "Feb. 22, 1996". This is followed by three pages appearing to describe an experiment and its results.
- g. The translation of lab notebook page M 002622 states, at the top of the page, "LTD -9 L3" and "Feb. 29, 1996". This is followed by three pages appearing to describe an experiment and its results.
- h. The translation of lab notebook page M 002626 states, at the top of the page, "LTD 11 L2" and "March 1, 1996". This is followed by four pages appearing to describe an experiment and its results.
- i. The translation of lab notebook page M 002631 states, at the top of the page, "LTD 10 L3" and "March 4, 1996". This is followed by two pages appearing to describe an experiment and its results.
- j. The translation of lab notebook page M 002634 states, at the top of the page, "LTD 12 L2" and "March 5, 1996". This is followed by one page appearing to describe an experiment and its results.
- k. The translation of lab notebook page M 002636 states, at the top of the page, "LTD 12 L2" and "March 6, 1996". This is followed by four pages appearing to describe an experiment and its results.
- I. The translation of lab notebook page M 002639 states, at the top of the page, "LTD 12 L2" and "March 7, 1996". This is followed by one page M 002640 appearing to describe an experiment and its results. On that page, it states "(Continues on page 1 of Lola's notebook 1)."
- m. The translation of lab notebook page M 002644 states, at the top of the page, "LTD -6 L1" and "March 7, 1996". This is followed by three pages appearing to describe an experiment and its results.

- n. The translation of lab notebook page M 002648 states, at the top of the page, "LTD -6 L2" and "March 11, 1996". This is followed by two pages appearing to describe an experiment and its results. On page M 002650, it states "(CONTINUES on page 2 of Lola's notebook 1)."
- o. The translation of lab notebook page M 002666 states, at the top of the page, "March 19, 1996" and "Purification Tests of Raw LTD-6-L3." This is followed by two pages appearing to describe results for LTD-6-L3.
- p. The translation of lab notebook page M 002667 states, at the top of the page, "March 20, 1996" and "LTD-6-L3/P2."
- q. The translation of lab notebook page M 002672 states, at the top of the page, "March 20, 199[6]" and "LTD-13-L1 Purification Tests." It also states: "LTD-13-L1/P1 (see page 12, notebook 1, Lola)."
- r. The translation of lab notebook page M 002684 states, at the top of the page, "LTD 13 L2" and "March 25, 1996". On that page, it states "Reference: Same as L1 (Lola's notebook, page 11)." This is followed by two pages appearing to describe an experiment and its results.
- s. The translation of lab notebook page M 002758 states, at the top of the page, "LTD L1" and "March 27, 1996". This is followed by five pages appearing to describe an experiment and its results.
- t. The translation of lab notebook page M 002703 states, at the top of the page, "LTD 11 L4" and "April 1, 1996". This is followed by one pages appearing to describe an experiment and its results.
- u. The translation of lab notebook page M 002773 states, at the top of the page, "LTD L3" and "April 23, 1996". This is followed by three pages appearing to describe an experiment and its results.
- v. The translation of lab notebook page M 002754 states, at the top of the page, "Intermediate Analysis by Morepen Laboratories, Limited" and "May 2, 1996". On this page, referring to LTD-6-L3/P2 and LTD-13-L1/P1, it states "both of which were identified as correct by Dr. Pelayo Camps."
- w. The translation of lab notebook page M 002752 states, at the top of the page, "Purification of Cycloheptanone" and "May 6, 1996". The following words are also included: "(see also page 67 of Notebook I, kept by Lola)." This is followed by one page appearing to describe an experiment and its results.

- x. The translation of lab notebook page M 002832 states, at the top of the page, "LTD L13" and "June 6, 1996". This is followed by four pages appearing to describe an experiment and its results.
- y. The translation of lab notebook page M 002837 states, at the top of the page, "LTD L14" and "June 11, 1996". This is followed by four pages appearing to describe an experiment and its results.
- z. The translation of lab notebook page M 002842 states, at the top of the page, "LTD L15" and "June 12, 1996". This is followed by four pages appearing to describe an experiment and its results.
- aa. Other than referring to "Lola" or "Pelayo Camps" on various pages (see supra), there is no name or signature on any of the pages.
- 46. Exhibit 2035 consists of, in the following order:
- (1) an untranslated copy of eight pages of a lab notebook marked Exhibit 47 and Plaintiff's Exhibit 21;
- (2) a copy of an affidavit from Fernando Feliu-Moggi stating that attached Exhibit A is a translation he believes to be a true Catalan to English translation of the document marked M 002795 M 002802;
 - (3) a sheet marked "Exhibit A";
 - (4) a copy of the translation; and,
- (5) a copy of lab notebook pages marked M 002795 M 002802, which are identical to (1).
- a. The translation of lab notebook page M 002795 states, at the top of the page, "LTD –L6" and "May 7, 1996".
- b. The translation of pages M 002796 M 002799 describes a procedure for obtaining "99.9 % raw LTD-L6," page M 002799.

- c. The translation of page M 002800 is entitled "Thin-Layer [Chromatography]:" and includes three boxes, each indicating "illegible chromatogram."
- d. The translation of page M 002801 is entitled "LTD-L6/P" and dated "May 8, 1996".
- e. The translation of page M 002802 is entitled "LTD-L6/P1" and dated "May 9, 1996".
 - f. There is no name on any of the pages.
- 47. Exhibit 2036 consists of, in the following order:
- (1) an untranslated copy of a single-page document marked Plaintiff's Exhibit 22;
- (2) a copy of an affidavit from Fernando Feliu-Moggi stating that attached Exhibit A is translation he believes is a true Spanish to English translation of the document M 002803;
 - (3) a sheet marked "Exhibit A";
 - (4) a copy of the translation; and,
 - (5) a copy of a page marked M 002803 which is identical to (1).
- a. According to the translation, the untranslated copy of the single-page document marked Plaintiff's Exhibit 22, or M 002803, is entitled "Medichem S.A. Research & Development (R&D) Department."
 - b. The translation states the following:
 - "Characterization request No.: 37/96"
 - "Request date: May 9, 1996"
 - "Product name: LORATADINE"
 - "Reference No.: LTP-L6/P1"
 - "Project name: LTD"

- c. The translation includes boxes for "Chemical structure"; "Solubility"; Characterization requested"; and "Remarks," which are either empty or have little information.
- d. The translation ends with the words "[signature]" and "May 9, 1996."
- 48. <u>Exhibit 2037</u> consists of, in the following order:
- (1) an untranslated copy of a single-page document marked Plaintiff's Exhibit 24;
- (2) a copy of an affidavit from Fernando Feliu-Moggi stating that attached Exhibit A is translation he believes is a true Spanish to English translation of the document M 002553;
 - (3) a sheet marked "Exhibit A";
 - (4) a copy of the translation; and,
 - (5) a copy of a page marked M 002553 which is identical to (1).
- a. According to the translation, the untranslated copy of the single-page document marked Plaintiff's Exhibit 24, or M 002553, is entitled "Medichem S.A. Research project: LORATADINE"
 - b. The translation states the following:
 - "4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidine ethyl carboxylate (Reference: LTD L6/P1)"
- c. The translation appears to include two sets of NMR spectral data and adds two "Notes."
 - d. The translation provides the following statements:
 - "The spectral data for this sample were perfectly consistent with the data obtained previously for LTD No. 50111006.
 Thus, we can conclude that the substance in question is loratedine."

- e. The translation ends with the words "Barcelona June 3, 1996" and "[signature:] Pelayo Camps."
- 49. Exhibit 2039 consists of a copy of a four-page document
- a. The first page is marked Plaintiff's Exhibit 23. The last three pages are marked M 002829, M002830 and M002831.
 - b. Each page presents a different graph.
 - c. At the bottom of each graph, the following words are included:
 - "P. Camps cdc13 LTD-L6-L1;" and,
 - "exp May 15 96 300."
- 50. Exhibit 2041 is a 19 page document that appears to be a copy of a transcript prepared by the Ellen Grauer Court Reporting Co.
- a. The first page is entitled "Medichem vs. Rolabo Gloria Rodriguez 11/9/01 Confidential Page 1 to page 72."
- b. On the top margin of the first page, it is indicated that the document is "Court Exhibit 5." Also, there is a hand-written notation, apparently signed by U.S District Judge Jed S. Rakoff on April 28, 2002, that reads "Court's rulings: "S" = objection sustained. "O" = objection overruled."
- c. Each of the next eighteen pages consists of four panels. Each panel is headed by a page number, beginning with page 1 for the first panel on the second page of the document and ending with page 72 on the last panel on page 18 of the document.
- d. The first panel ("Page 1") states: "Videotaped Confidential Deposition of Medichem, S.L., by Gloria Rodriguez, taken pursuant to 30(b)(6) Notice and Stipulations ..."
- e. According to the panels marked "Page 43, " Page 44," and "Page 45," Rodriguez was asked about experiments recorded in Exhibits 47 [See Exhibit 2035] discussed above] and 48.
 - f. Apparently, Rodriguez:
 - did not recall if Exhibit 47 was the first time Medichem successfully obtained loratedine via the McMurry reaction;

- did not know if loratadine was obtained in the test in Exhibit 47;
- stated that "Pursuant to the details which are recorded here [i.e., Exhibit 47], the results of the test which appear here, my answer I, yes;"
- did not recall why pyridine was used in LTD-L6;
- did not know where the sample of LTD-13 used in LTD-L6 was obtained from;
- stated that "according to what is recorded here [i.e., Exhibit 47], it was a commercial cycloheptanone;"
- stated that "According to the reference recorded here [i.e., "M797," which is said to have been provided to her] it would have come from Morepen laboratories;" and,
- stated, when asked "Why do you suppose you've seen Exhibit 48?", "because the table shows all the trials run on loratadine, They're recorded in our notebooks, but from memory, I don't recall."
- g. In the margin of the panels marked "Page 43, " Page 44," and "Page 45," there are hand-written notations, including the letters "H," "A," "S" and "O."
- 51. Exhibit 2042 appears to be a copy of a provisional application for patent. Included is a cover sheet marked Exhibit 60, which appears to be in Spanish and is not translated. Attached thereto, as pages M 003724-3738, in English, is a description of a process for the preparation of loratedine, claims, an abstract of the disclosure, a declaration for patent application, assignment and a verified statement claiming small entity status.
- 52. Exhibit 2043 appears to be a copy of eight pages from a lab notebook.
 - a. None of the pages are translated.
 - b. There is no name on any of the pages.
- c. The first page is marked as Exhibit 43. "LTD-L1" and "27/3/96" are at the top of the page.

- d. The following seven pages are marked as M 002759 2765.
- e. "LTD-L1" and "09/04/96" are at the top of the seventh page; i.e., M 002764.
 - f. "10/06/96" is indicated on the last page; i.e., M 002765.
- 53. <u>Exhibit 2044</u> appears to be a copy of seven pages from a lab notebook.
 - a. None of the pages are translated.
 - b. There is no name on any of the pages.
- c. The first page is marked as Exhibit 46. "LTD-L12" and "15/4/96" are at the top of the page.
 - d. The following six pages are marked as M 002767 2772.
 - e. "18/04/96" is indicated on the fifth page; i.e., M 002770.
 - f. "19/04/96" is indicated on the sixth page; i.e., M 002771.
 - g. "20/04/96" is indicated on the seventh page; i.e., M 002772.
- 54. Stampa would have us believe that the evidence (i.e., <u>Exhibit 2021</u>) suggests that Medichem first made loratadine by the McMurry reaction on May 7, 1996.
- 55. Stampa would have us believe that the evidence (i.e., <u>Exhibit 2035</u>) suggests that trial LTD-L6 was conducted on May 7, 1996.
- The lab notebook page (i.e., M 002795 of Exhibit 2035) that is said to record trial LTD-L6 has no name or signature but includes "LTD-L6" and "May 7, 1996."

- 57. Stampa would have us believe that the evidence (i.e., <u>Exhibit 2095</u>) suggests that trial LTD-L6 represents the first time Medichem made loratadine by the McMurry reaction.
- 58. Stampa would have us believe that the evidence (i.e., <u>Exhibit 2024</u>, at ¶ 11) suggests that Lola Casas, a noninventor, conducted trial LTD-L6.
- 59. Stampa would have us believe that the evidence (i.e., Exhibit 2024, at ¶ 11 and Exhibit 2027) suggests that Lola Casas was Rodriguez' assistant at the time trial LTD-L6 was conducted on May 7, 1996.
- 60. Stampa would have us believe that the evidence (Exhibits 2022, 2037 and 2039) suggests that the product Medichem first obtained on May 7, 1996 from trial LTD-L6 was verified as being loratedine.
- 61. Stampa would have us believe that the evidence (i.e., <u>Exhibit 2021</u>) suggests that Medichem first made loratedine by the McMurry reaction on May 7, 1996.
- 62. Stampa would have us believe that the evidence (i.e., Exhibit 2035) appears to suggest that trial LTD-L6 was conducted on May 7, 1996.
- 63. All the evidence regarding an experiment on May 7, 1996 which is said to have obtained loratedine via a process of the count and conducted by Lola Casas and said to be recorded on M 002795 of Exhibit 2035 is based on the testimony of the inventors Bosch, Camps, Onrubia and Rodriguez.
- 64. There is no testimony from Lola Casas.

I. Corroboration

- 65. Stampa argues that the evidence, represented by Exhibits 2049, 2055 and 2056, shows weekly reports on the status of the project to make loratedine via the McMurry reaction were prepared and that "[t]hese weekly reports appear to be regular business records made contemporaneously with the inventive process and are, thus corroborative evidence of reduction to practice according to the "rule of reason" analysis." Stampa's Brief, p. 11.
- 66. The corroborative evidence put forward by Stampa (Stampa's Brief, pp. 10-12) consists of:
 - "Declaration of John G. Taylor," Exhibit 2049, ¶¶ 12-13;
 - Bosch's partial testimony in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087, on May 1, 2002, Exhibit 2055, pp. 281-83; and,
 - Exhibit 2056, specifically pages M 006335, 41¹¹, 44, 48, 54, 58, 62, 66, 72, 83, 88, 93 and 99.
- 67. Regarding the "Declaration of John G. Taylor," Exhibit 2049, ¶¶ 12-13:
 - a. John G. Taylor is an attorney for Stampa;
- b. \P 12 there is no \P 12 in the document we received as Exhibit 2049; and,
- c. ¶ 13 Taylor declares that "Exhibit 2056 contains true and correct copies of Weekly Reports from Dr. Jordi Bosch at Medichem's laboratory in Celra, Spain to Dr. Carmen Onrubia at Medichem's headquarters in Barcelona, Sapin for the period march 23, 1996 through May 10, 1996."
- 68. Bosch's partial testimony in Medichem, S.A. v. Rolabo, S.L., 01 Civ. 3087, on May 1, 2002, Exhibit 2055, pp. 281-83, indicates that Bosch concurred that

¹¹ In relation to page M 006341 of Exhibit 2056, Stampa further refers to Exhibit 2037. See lines 10-12, page 11of Stampa's Brief. Exhibit 2037 is described above in Fact 47.

he prepared weekly reports during the course of 1995 and 1996 from him to Onrubia at Medichem's headquarters.

- 69. Regarding Exhibit 2056, most of it is redacted and none of it translated.
 - On various cover sheets (e.g., M006336), it states "De/From: Jordi Bosch," "Per/To: Medichem, S.A.," and "Attn: Dra. M.C. Onrubia."
 - M 006335 there is a notation at the top that appears to say "Attn Sr. J.A. Pena";
 - M 006341 in the middle its says "Loratadina via Reaccion McMurry (Ti(0))" and "LTD-6" and in the top margin the date appears to be indicated as "10/5/96";
 - M 006344 there is a notation at the top that appears to say "Attn Sr. J.A. Pena" and appears to be signed by Onrubia on "6/5/96";
 - M 006348 in the middle its says "Loratadina via Reaccion McMurry (Ti(0))" and in the top margin the date appears to be indicated as "6/5/96"; LTD-6 is not mentioned;
 - M 006354 -there is a notation at the top that appears to say "Attn Sr. J.A. Pena" and appears to be signed by Onrubia on "6/5/96"; in the middle its says "Loratadina" and the date "03-May-96" is indicated;
 - M 006358 near the top its says "Loratadina via Reaccion McMurry (Ti(0))" and in the top margin the date appears to be indicated as "29/4/96"; LTD-6 is not mentioned;
 - M 006362 there is a notation at the top that appears to say "Attn Sr. J.A. Pena" and appears to be signed by Onrubia on "15/4/96"; "Loratadina" is mentioned near the bottom; and in the top margin the date appears to be indicated as "15/4/96";
 - M 006366 in the middle its says "Loratadina via Reaccion McMurry (Ti(0))"; LTD-6 is not mentioned;
 - M 006372 in the middle its says "Loratadina via Reaccion McMurry" (Ti(0))"; LTD-6 is not mentioned;
 - M 006383 there is a notation at the top that appears to say "Attn Sr. J.A. Pena"; "Loratadina" is mentioned near the bottom; and in the top margin the date appears to be indicated as "1/4/96";
 - M 006388 in the middle its says "Loratadina via Reaccion McMurry (Ti(0))"; LTD-6 is not mentioned; and in the top margin the date appears to be indicated as "31/3/96";
 - M 006393 there is a notation at the top that appears to say "Attn Sr. J.A. Pena" with the date "26/3/96"; "Loratadina" is mentioned near the bottom; and in the top margin the date appears to be indicated as "25/3/96"; and,

- M 006399 in the middle its says "Loratadina via Reaccion McMurry (Ti(0))"; LTD-6 is not mentioned; and in the top margin the date appears to be indicated as "25/3/96".
- 70. Page M 006341 appears to be the most relevant of the pages of Exhibit 2056 because it states "LTD-6" and "10/5/96". However, because of the lack of translation, we are unable to determine what happened on that date.
- 71. The corroborative evidence put forward by Stampa is either from an attorney for the inventors or the inventors themselves.
- 72. There is no testimony from "Sr. J. A. Pena," a noninventor noted on the top of various pages in Exhibit 2056 (see above).

III. Discussion

Stampa has the burden to prove priority.

To prevail on priority, Stampa must establish by a preponderance of the evidence that it invented the interfering subject matters of both Count 1's prior to February 26, 1997, the priority benefit date accorded Jackson.

Stampa's case on priority appears to be based on the legal theory that it actually reduced the invention of the counts to practice no later than May 7, 1996; i.e., before Jackson's February 26, 1997 priority benefit date. Stampa bases its legal theory on an experiment, denoted "LTD-L6," that Stampa alleges was performed on May 7, 1996 by Lola Casas under the supervision of inventor Rodriguez.

The issue is whether a preponderance of the evidence supports Stampa's allegation that it performed an experiment on May 7, 1996 meeting the invention of the counts. We find that it does not.

A. Actual Reduction to Practice

We have reviewed the section on actual reduction to practice presented in Stampa's brief (pp. 9-10) and find Stampa's discussion on the matter deficient.

Assuming an experiment took place on May 7, 1996, what actually happened in that experiment is never explained.

On the question of actual reduction to practice, Stampa's brief starts with an allegation:

"Stampa [actually] reduced to [sic] the invention to practice by preparing loratedine according to the process of Count 1 no later than May 7, 1996."

Paper 81, at page 9, line 17-18. This is followed by three statements (p. 9, line 17 to p. 10, line 9):

- On that date [i.e., May 7, 1996], Medichem employee Lola Casas, working under the supervision and control of Gloria Rodriguez (a Medichem employee and named inventor on Stampa's '100 patent and reissue application), successfully carried out a trial of the process later claimed in the '100 patent and reissue application and made loratadine."
- "The trial was denoted 'LTD-L6' in Medichem's laboratory notebooks to signify Medichem's sixth trial to obtain loratedine via the process of Count 1."
- "Unlike prior trials, however, in LTD-L6 Medichem used a starting material (Formula VII of claim 1 of Stampa's '100 patent and reissue application) that it purchased from a commercial supplier, rather than staring material

it had produced itself and used in the five previous trials LTD-L1 through LTD-L5)."

Each of these statements is followed by a list of exhibits. That is the extent of the discussion in Stampa's brief about the alleged May 7 experiment.

Stampa's brief does not explain the May 7 experiment. What was entailed in performing the experiment is not discussed. The steps involved in the process are not mentioned. Stampa states that Lola Casas successfully carried out a trial of the process on May 7, but what she did to successfully carry out the trial is not explained. Nothing is said about the experiment itself or what Lola Casas did. No amounts, ingredients, temperatures, times, etc. are discussed. The steps she took are not discussed. We simply do not know what happened on May 7, 1996.

Because we are not told what happened on May 7, 1996, we have no way of knowing whether the May 7 experiment meets the elements of the counts.

The rule is as follows:

In an interference proceeding, a party seeking to establish an actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment or performed a process that met every element of the interference count, and (2) the embodiment or process operated for its intended purpose.

Eaton v. Evans, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

The first prong requires Stampa to show that it performed a process that meets every element of the interference counts. Stampa has not shown that a reaction was conducted in the presence of a low valent titanium generated by zinc. This is an element of the counts. Stampa must show an experiment was

performed with a low valent titanium generated by zinc to establish that it actually reduced an invention of the counts to practice. That has not been shown. For that matter, Stampa nowhere shows an experiment having been performed that meets any element of any count¹².

As far as the exhibits are concerned, they, too, are not analyzed. Given that they are listed at the end of the statements, presumably they are relevant to what is alleged in the statements. But we are given no further guidance. It is left to us to go through the exhibits and figure out where and if they disclose what Stampa says they disclose.

Stampa's legal theory is that it actually reduced the invention of the counts to practice no later than May 7, 1996 when Lola Casas, under the supervision of inventor Rodriguez, performed an experiment, denoted "LTD-L6," on May 7, 1996. Coupled with the fact that Stampa has failed to explain what happened during the alleged May 7 experiment, the citing of numerous exhibits without discussion, amounts to an invitation for the Board to pour over the evidence to discover relevant information to support Stampa's legal theory. We decline the invitation.

It is not the Board's responsibility to research the exhibits and construct Stampa's argument Cf. United States v. Lanzotti, 205 F.3d 951, 957 (7th Cir.

¹² Stampa argues that "Stampa [actually] reduced to [sic] the invention to practice by preparing loratedine according to the process of <u>Count 1</u> no later than May 7, 1996." However, there are two Count 1's and they are not the same. Count 1 of 105,212 is narrower in scope than Count 1 of 105,069. Stampa has not shown that the LTD-L6 experiment meets every element of both counts.

2000) ("The premise of our adversarial system is that appellate courts do not sit as self-directed boards of legal inquiry and research, but essentially as arbiters of legal questions presented and argued by the parties before them,' <u>Carducci v. Regan</u>, 714 F.2d 171, 177 (D.C.Cir. 1983 (Scalia, J.)."). It is not the Board's job to scour the record, research any legal theory, and serve generally as an advocate for a party. <u>Ernst Haas Studio, Inc. v. Palm Press, Inc.</u>, 164 F.3d 110, 111-12, 49 USPQ2d 1377, 1378-79 (2d Cir. 1999).

B. Corroboration

Stampa has not explained the experiment allegedly performed on May 7, 1996 with any specificity to persuade us that that experiment was an actual reduction to practice of the invention of the counts.

Moreover, the alleged May experiment itself has not been sufficiently corroborated.

Rodriguez has declared (Exhibit 2024) that Lola Casas, as her assistant, conducted the LTD-L6 trial on May 7, 1996 and recorded it in the lab notebook pages of Exhibit 2035¹³. This appears to be the only evidence mentioning Lola Casas and connecting her to the May 7 experiment. However, Rodriguez is an inventor. Her statements are considered self-serving unless there is independent evidence to corroborate the statements.

¹³ Exhibit 2035 is said to be a copy of the lab notebook pages on which trial LTD-L6 is recorded. The terms "LTD-L6" and "May 7, 1996" are indicated on page M002797. There is no name and no signature on any of the pages.

The rule is:

The inventor, however, must provide independent corroborating evidence in addition to his own statements and documents. See Lacotte v. Thomas, 758 F.2d 611, 613, 225 USPQ 633, 634 (Fed. Cir. 1985). Such evidence "may consist of testimony of a witness, other than an inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor."

Reese v. Hurst v. Wiewiorski, 661 F.2d 1222, 1225, 211 USPQ 936, 940 (CCPA 1981). See also Lacotte v. Thomas, 758 F.2d at 613, 225 USPQ at 634 (citing Reese); 37 C.F.R. §1.608(b).

Hahn v. Wong, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989).

As evidence of corroboration, Stampa (brief, pp. 10-12) provides what are said to be (1) a declaration from John G. Taylor (Exhibit 2049), (2) testimony given by Bosch in the District Court (Exhibit 2055) and (3) weekly reports (Exhibit 2056).

John G. Taylor is an attorney for Stampa. We do not see how statements made by Stampa's attorney can be credited as to an actual reduction to practice said to have occurred as a result of an experiment performed by Casas (Exhibit 2049). Indeed, Taylor's testimony is apparently based upon reports from Bosch, one of the named inventors.

The same can be said of Bosch's statements (Exhibit 2055) said to have been given during the District Court trial. These statements are from an inventor and, as such, are not independent of the inventors.

Finally, with respect to the weekly reports (Exhibit 2056) to which both Taylor and Bosch refer, they are not translated and largely redacted. Their relevance and, if relevant, their weight cannot be determined.

We find that Stampa has provided no convincing evidence independent of the inventors to corroborate statements made as to an experiment (LTD-L6) said to have been conducted on May 7, 1996 by Rodriguez's assistant, Lola Casas.

The best evidence of corroboration would have been the testimony of Lola Casas, a non-inventor, and apparently the person who conducted LTD-L6, the sole experiment relied upon to show an invention of the counts was actually reduced to practice on May 7, 1996. Accordingly, her testimony would have been highly probative in establishing that the experiment said to have been conducted by Casas on May 7, 1996 on behalf of Rodriguez was in fact conducted on May 7, 1996 and it is the experiment said to be recorded in the lab notebook pages of Exhibit 2035. In fact, given that Lola Casas is said to have performed the LTD-L6 trial, she is in the best position to explain the May 7 experiment as well as the contents of the lab notebook pages of Exhibit 2035 said to be a record of her activities related to the May experiment. Her explanation would have been helpful in determining whether trial LTD-L6 met all the elements of the counts. Lola Casas' testimony would have been crucial in corroborating inventors' testimony that a process meeting the counts was performed on May 7, 1996. However, Lola Casas did not testify.

Given its significant potential to corroborate Stampa's alleged May 7 experiment, we could draw an adverse inference against Stampa for failing to put such crucial testimony before the Board. Cf. Revson v. Cinque & Cinque, P.C., 221 F,3d 71, 81-82 (2d Cir. 2000) ("It is well-settled that a party's failure to call a witness may permissibly support an inference that witness's testimony would have been adverse.") However, because Stampa's case is so weak, we find it unnecessary to draw an inference one way or the other.

Because there is insufficient independent evidence to corroborate the May 7, 1996 experiment and the best evidence of corroboration – Lola Casas' testimony - has not been provided, we find that Stampa has failed to establish that the May 7, 1996 experiment is an actual reduction to practice of the invention of the counts by a preponderance of the evidence.

IV. Priority Decision

Stampa has not proved it actually reduced the invention of the counts to practice no later than May 6, 1997, by a preponderance of the evidence, 37 CFR § 41.207(a)(1), and therefore Stampa has not overcome the presumption that Jackson first invented the interfering subject matter of Count 1 of both interferences.

V. District Court Action

We appear to reach a result opposite from that reached by the United States District Court for the Southern District of New York in MediChem, S.A. v. Rolabo, S.L., Civ. Action No. 01-CV-3087 (JSR).¹⁴

According to the Memorandum Order issued November 19, 2004, p. 8

(see Paper 111), "the Court, having considered the priority issue once again, reconfirms and reinstates its prior finding and resolves the priority determination in favor of Medichem [i.e., Stampa]."

In the prior finding¹⁵, the District Court stated that "both documents and the testimony and evidence of Medichem's reduction to practice of its invention in the Spring of 1996 is so strong as to overcome any doubt that the Court may

As a matter of background, Stampa et al.'s U.S. Patent 6,084,100 and Jackson's U.S. Patent 6,093,827 were involved in a civil action under 35 U.S.C. §291 (judicial interference) in the United States District Court for the Southern District of New York. MediChem, S.A. v. Rolabo, S.L., Civ. Action No. 01-CV-3087 (S.D.N.Y., filed May 7, 2002). In that action, the District Court stated that, notwithstanding that it found in favor of Medichem [i.e., Stampa] on the question of priority, it "found in favor of defendant [Rolabo; i.e., Jackson] of plaintiff's claim for interference for the reasons state [sic, stated] from the bench on May 7, 2002." The Court decided that no interference-in-fact existed and, on those grounds, Jackson prevailed in the action.

The Federal Circuit reversed and remanded for further proceedings on the question of whether an interference-in-fact existed. MediChem, S.A. v. Rolabo, S.L., 353 F.3d 928 (Fed. Cir., 2003).

The District Court reconsidered its position on the question of interference and ruled that an interference-in-fact did exist. <u>See</u> the <u>Memorandum Order</u> in <u>MediChem, S.A. v. Rolabo, S.L.</u>, Civ. Action No. 01-CV-3087, on remand from the Fed. Circuit, on November 19, 2004. The Court reinstated and reaffirmed its former priority ruling in favor of Medichem (i.e., Stampa et al.). Judgment was awarded in favor plaintiff Medichem (i.e., Stampa et al.).

¹⁵ The prior finding on priority to which the District Court refers is in MediChem, S.A. v. Rolabo, S.L., Civ. Action No. 01-CV-3087 (S.D.N.Y., filed May 7, 2002) (see Jackson Exhibit 1001).

have had in this regard."16 However, we have been unable to determine the precise reasoning leading it to the Court's conclusion. We do not know whether the evidence that led the Court to that conclusion is the same as the evidence before us. Also, it is not entirely clear to us what the Court defined to be the interfering subject matter.

The question here under the rubric of priority is to determine when each party's patented invention was first reduced to practice. As mentioned, the inventions here are processes for the preparation of loratadine. Regarding plaintiff's process [Medichem, i.e., Stampa], it is virtually conceded that Plaintiff's Exhibit 87, which purported to attest that Medichem patent was reduced to practice in 1995, was a fraudulently backdated document. More generally, I do not find sufficient evidence that establishes that plaintiff's process was reduced to practice in 1995.

However, I do not share defendant's view that this fact cast meaningful doubt on the substantial documentation and testimony that the Medichem invention was reduced to practice in the Spring of 1996. For one thing, I credit the testimony of plaintiff's witnesses that the backdating was chiefly a belated attempt to deal with their noncompliance with the ISO regulatory requirements. It is true that the willingness of Medichem to fraudulently backdate Plaintiff's Exhibit 87, coupled with Medichem's less than punctillious record keeping practices - as evidenced most recently by its failure to produce very important documents in this case until shortly a week before trial, and only then after they had been referenced in the parallel Spanish litigation - does convince the Court that it cannot place the same reliance on plaintiff's testimony and documents as it might otherwise have. Nonetheless, both documents and the testimony and evidence of Medichem's reduction to practice of its invention in the Spring of 1996 is so strong as to overcome any doubt that the Court may have had in this regard. See, in this regard Plaintiff's Exhibits 22 (Exhibit 2036), 23 [Exhibit 2039], 24 [Exhibit 2037], just by way of examples. By contrast, defendant, by its own position, does not claim that its reduction to practice occurred before the fall of 1996. And so, accordingly, I find that plaintiff has established priority.

Jackson Exhibit 1001, pp. A00009-10.

¹⁶ The entire passage reads:

VI. JUDGMENT

For the foregoing reasons, judgment as to the subject matter of Count 1 in interference 105,069 and 105,212 will be entered against junior party Stampa.

FRED E. McKELVEY
Senior Administrative Patent Judge

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